Does the envisioned ultimate utility address an unmet clinical need?

Is the work focussed primarily on the discovery/development of the BM for application to clinical material?

Is there a sample collection for retrospective BM – cancer detection correlation studies (i.e. for BM Discovery – Stages 1/2)?

Further basic research or sample access required or redirect research effort elsewhere

Do you have a BM assay?

Define BM specificity using samples representative of the target population, BIDD BM Discovery – Stage 1

Can the biomarker distinguish between subjects with & without cancer?

Refinement of assay: Definition of SOPs and assay performance BIDD Assay Development Stage 2

Study the relationship between the BM and clinical outcome using retrospective longitudinal collections, Phase III* BIDD BM Discovery – Stage 2

Can the BM detect cancer earlier than the time of clinical diagnosis?

Develop clinical grade BM assay to appropriate standards. Assay should be fit for purpose BIDD Assay Development Stage 3

Validate correlation of BM with incidence as a primary/secondary endpoint in a large prospective study - determine detection rate/false referral rate, Phase IV* BIDD BM Qualification – Stage 1

Can the assay or study design be improved?

Is the correlation statistically robust?

Estimate reduction in cancer mortality afforded by the BM in a prospective randomised clinical trial, Phase V* PBSC/CTAAC BM Qualification – Stage 2

Does the use of the BM reduce cancer mortality?

Introduce the BM into routine primary care

* Pepe et al, 2001

Yes
No
Not Always Required

Rationale

SCREENING BIOMARKER (BM) ROADMAP

Biomarker Discovery and Assay Development

Biomarker Qualification

Development of an accurate/reproducible assay to measure BM Phase II* BIDD Assay Development – Stage 1

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